This document is scheduled to be published in the Federal Register on 01/04/2018 and available online at <a href="https://federalregister.gov/d/2017-28497">https://federalregister.gov/d/2017-28497</a>, and on FDsys.gov

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10518]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: *OIRA\_submission@omb.eop.gov* 

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

https://www.cms.gov/Regulations-and-

Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html

2. E-mail your request, including your address, phone number, OMB number, and CMS

document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44

U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and

Budget (OMB) for each collection of information they conduct or sponsor. The term "collection

of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency

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requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; Use: Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting.

On September 29, 2017, the "Disaster Tax Relief and Airport and Airway Extension Act of 2017" was enacted into law. Section 302 of this legislation extends the Medicare IVIG Demonstration through December 31, 2020. While existing beneficiaries enrolled in the demonstration as of September 30, 2017 will be automatically re-enrolled, in order to continue to

enroll new beneficiaries into the demonstration, an application is required. The original enrollment and financial limits remain and CMS will continue to monitor both to assure that statutory limitations are not exceeded.

This collection of information is for the application to participate in the demonstration. Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they are would be eligible for in the absence of the demonstration. Form Number: CMS-10518 (OMB control number: 0938-1246); Frequency: Annually; Affected Public: Individuals and households; Number of Respondents: 1,220; Total Annual Responses: 1,220 Total Annual Hours: 305. (For policy questions regarding this collection contact Jody Blatt at 410-786-6921.)

Dated: December 29, 2	2017.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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